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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,937	11/26/2003	Paul J. Gerwin	132386SV/YOD GEMS:0254	9428

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Patrick S. Yoder
FLETCHER YODER
P.O. Box 692289
Houston, TX 77269-2289

EXAMINER	
AZARIAN, SEYED H	

ART UNIT	PAPER NUMBER
2624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,937	GERWIN, PAUL J.	
	Examiner	Art Unit	
	Seyed Azarian	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25-30* is/are allowed.

6)☒ Claim(s) *1,3-10 and 13-24* is/are rejected.

7)☒ Claim(s) *2,11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/26/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 26 and 27 objected, as being in improper form, because claims 26 and 27, Misnumbered as depended to claims 26 and 27 and must be renumbered to indigested claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 24 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 24 define " a computer program for testing an imaging device, the computer program being located on one or more tangible media, comprising" embodying functional descriptive material. However, the claim does not define a "computer-readable medium, memory or computer readable medium encoded with a computer program, such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer which permit the computer program's functionality to be realized and are only statutory when recited as being embodied in a computer-readable storage medium.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-5, 8-10, 13-18, 20-24, are rejected under 35 U.S.C. 102(b) as being anticipated by Launay et al (U.S. patent 6,224,257).

Regarding claim 1, Launay discloses a phantom for use with an imaging device, comprising (column 3, lines 13-18, to simulate a rotating acquisition of images of the patient with a specific stimulation device also called "phantom").

a first portion including at least one group of vessel-like regions having a radiographically opaque quality, wherein the at least one group of vessel-like regions includes at least first and second vessel-like regions such that the first vessel-like region is larger than the second vessel-like region (column 2, lines 38-64, at least one image is acquired of a unit for simulating the patient's bones and soft tissue only, and at least one image is acquired of this unit and of the device for simulating the patient's opacified blood vessels, and using image subtraction, an image of the simulation device is obtained, also column 4, lines 8-22, provided with a succession of portions of large diameter and portion of small diameter, in order to make it possible to verify whether portions 26 and 27 are displayed satisfactorily);

and a second portion rotatably coupleable to the first portion, the second portion having a testing region of material radiographically similar to human tissue (column 1, lines 48-65, each wire can be disposed at a distance from the axis normal to the plane of rotation of the axis of the x-ray beam that is different from, also column 2, lines 38-64, at least one image is acquired of a unit for simulating the patient's bones and soft tissue and column 3, lines 13-18, in order to control the performance level of a three-dimensional angiography system, it is necessary to simulate a rotating acquisition of images of the patient with a specific simulated device called a "phantom").

Regarding claim 4, Launay discloses the phantom as recited in claim 1, wherein the testing region includes a first material radiographically similar to a first kind of human tissue and a second material radiographically similar to a second kind of human tissue (see claim 1, also column 2, lines 38-46, the patient's bones and soft tissue).

Regarding claim 8, Launay discloses the phantom as recited in claim 1, comprising an arm for rotating the 5 first portion with respect to the second portion (column 3, lines 13-18, in order to control the performance level of a three-dimensional angiography system, it is necessary to simulate a rotating acquisition of images of the patient with a specific simulated device called a "phantom").

Regarding claim 9, Launay discloses a phantom for use with an imaging device, comprising: a first portion having at least one group of vessel-like regions extending from a first portion central region and towards a periphery of the first portion, wherein the at least one group of vessel-like regions has a level of a radiographically opaque quality; and a second portion coupleable to the first portion and having a plurality of

testing regions arranged circumferentially with respect to one another, wherein each testing region includes an attenuation material radiographically similar to a kind of human tissue (see claim 1, also column 2, lines 38-46, the patient's bones and soft tissue and column 3, lines 19-33).

Regarding claim 13, Launay discloses the phantom as recited in claim 9, comprising a calibrating region (column 2, lines 47-64, refer to calibration).

Regarding claim 14, Launay discloses the phantom as recited in claim 9, wherein the calibrating region includes at least one of copper and water (column 4, lines 1, wires are made of copper).

Regarding claim 15, Launay discloses the phantom as recited in claim 9, wherein the first and second portions are couplable to one another such that the at least one group of vessel-like regions overlaps the plurality of testing regions (column 1, lines 52-59, device for simulating a patient's body is intended for the testing).

Regarding claim 17, Launay discloses the phantom as recited in claim 16, wherein the first kind of human tissue is bone tissue (column 2, lines 38-46, the patient's bones and soft tissue).

Regarding claim 18, Launay discloses the phantom as recited in claim 16, wherein the first kind of human tissue has a density greater than the second kind of human tissue (column 3, lines 19-33, the semi-circular elements 4 are made of a material with low X-ray absorption, for example polycarbonate, or another material of equiva-lent density. the simulation device comprises six semicircular elements 4

distributed uniformly in the circumferential direction. However, as a variant, it is possible to provide a different number, for example four or eight).

Regarding claim 21, Launay discloses the method as recited in claim 20, wherein producing comprises producing a digital X-ray image (column 2, lines 47-64, digital x-ray).

Regarding claim 22, Launay discloses the method as recited in claim 20, comprising stabilizing the imaging device via a calibration region located in the phantom (column 2, lines 47-64, refer to calibration).

With regard to claims 3, 5, 10, 16, 20 and 23-24, the arguments analogous to those presented above for claims 1, 4, 8, 9, 13 and 15 are respectively applicable to claims 3, 5, 10, 16, 20 and 23-24.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 6, 7 and 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over Launay et al (U.S. patent 6,224,257) in view of White et al (U.S. patent 6,992,280).

However regarding claims 6 and 7, Launay does not explicitly state its corresponding " wherein the radiographically opaque quality is a radio-opacity

equivalent to iodine or barium. On the other hand White in the same field of x-ray and calibration of image teaches (column 4, lines 48-59, x-ray contrast agent included barium or iodine compounds).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify, Launay invention according to the teaching of White because it containing compounds, which enhanced x-ray attenuation in the body zone into which they distribute for better accuracy in radiological imaging.

With regard to claim 19, the arguments analogous to those presented above for claims 6 and 7 are respectively applicable to claim 19.

Allowable Subject Matter

7. Claims 2, 11, and 12 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable claims

Claims 25-30 are allowable.

8. The following is an examiner's statement of reasons for allowance. Claim 25, representing claims 29 and 30, the closest prior art of record (Launay and White) does not teach or suggest, among other things, " a subtracted image of a phantom having a plurality of testing regions each region being configured to attenuate X-ray radiation at varying degrees arranged circumferentially with respect to one another and at least one group of vessel-like regions having a radiologically opaque quality overlapping arranged with respect to the circumferentially arranged testing regions, and analyzing the

subtracted image to determine the smallest vessel-like region of the vessel group of vessel-like regions visible in the test region having the highest degree of attenuation to determine an upper limit of the imaging device.

These key features in combination with other features of the claimed invention are neither taught nor suggested by the art of record.

Other prior art cited

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(U.S. patent 6,314,313) to Romeas et al is cited for device and process for simulating a patient's blood vessels.

(U.S. patent 7,125,166) to Eck et al is cited for method and device for automatic testing of an X-ray system.

(U.S. patent 6,582,368) to Holdaway et al is cited for medical instrument sheath comprising flexible ultrasound transducer.

(U.S. patent 6,845,142) to Ohishi is cited for image processing involving correction of beam hardening.

Contact Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (571) 272-7443. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella, can be reached at (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.
Status information about the PAIR system, see http:// pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Seyed Azarian
Patent Examiner
Group Art Unit 2624
June 16, 2007

Seyed azarian